Surveillance for Ventilator-Associated Pneumonia at CDC: Current Approach, Challenges, and Future Directions

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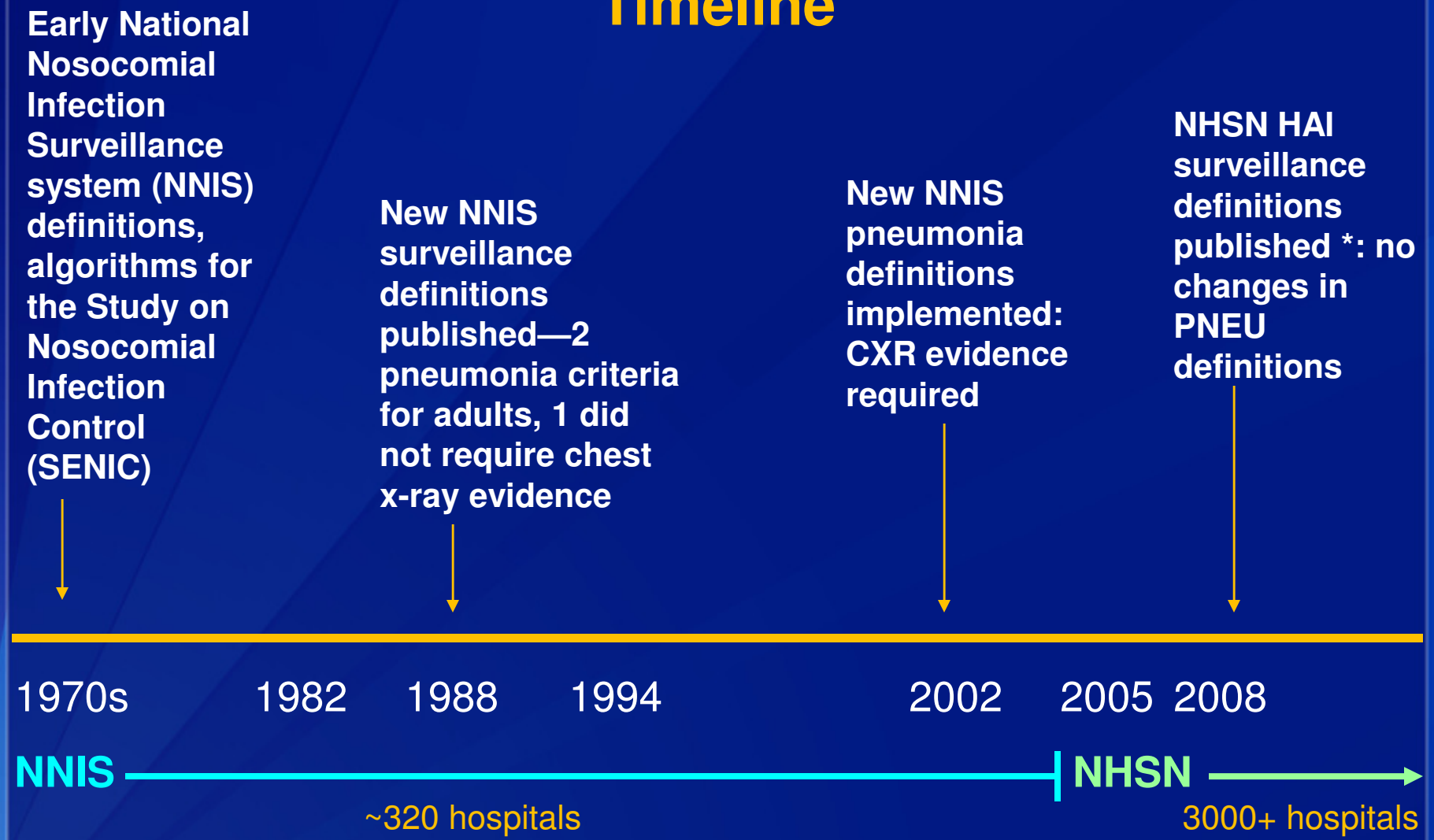
Overview

- **Timeline of healthcare-associated pneumonia surveillance at CDC**
- **Surveillance definitions of VAP**
  - Current National Healthcare Safety Network (NHSN) pneumonia (PNEU) definitions
  - NHSN user impressions of the definitions
- **Why is VAP so difficult?**
  - Clinical perspective
  - Surveillance perspective
- **What is the future of VAP surveillance?**
  - Draft definition of ventilator-associated lower respiratory infection definition (VALORI)
  - Early experience and feedback

Timeline



*Updated 3/2010, available at—http://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf

Review of Current NHSN PNEU Definitions

NHSN PNEU Definitions, 2002 to Present

- **In NHSN pneumonia (PNEU) is identified using a combination of x-ray, signs/symptoms and laboratory criteria.**
- **Three specific sets of PNEU criteria are available:**
  - PNU1 – Clinically Defined Pneumonia
  - PNU2 – Pneumonia with Laboratory Findings
  - PNU3 – Pneumonia in Immunocompromised Patients
- **PNU1, PNU2 and PNU3 can be used in any age patient**
  - Special PNU1 criteria that can be used in infants and children

See NHSN Manual: Patient Safety Component Protocol , http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf

Overview of PNEU Definition Criteria

- **No matter what PNEU definition is used …**
  - Chest imaging findings are required
  - Signs and symptoms of pneumonia are required (variant combinations permitted for immunocompromised patients, infants and children)
  - Laboratory evidence is NOT required—but if available (from an acceptable specimen type), should be used to report pneumonia

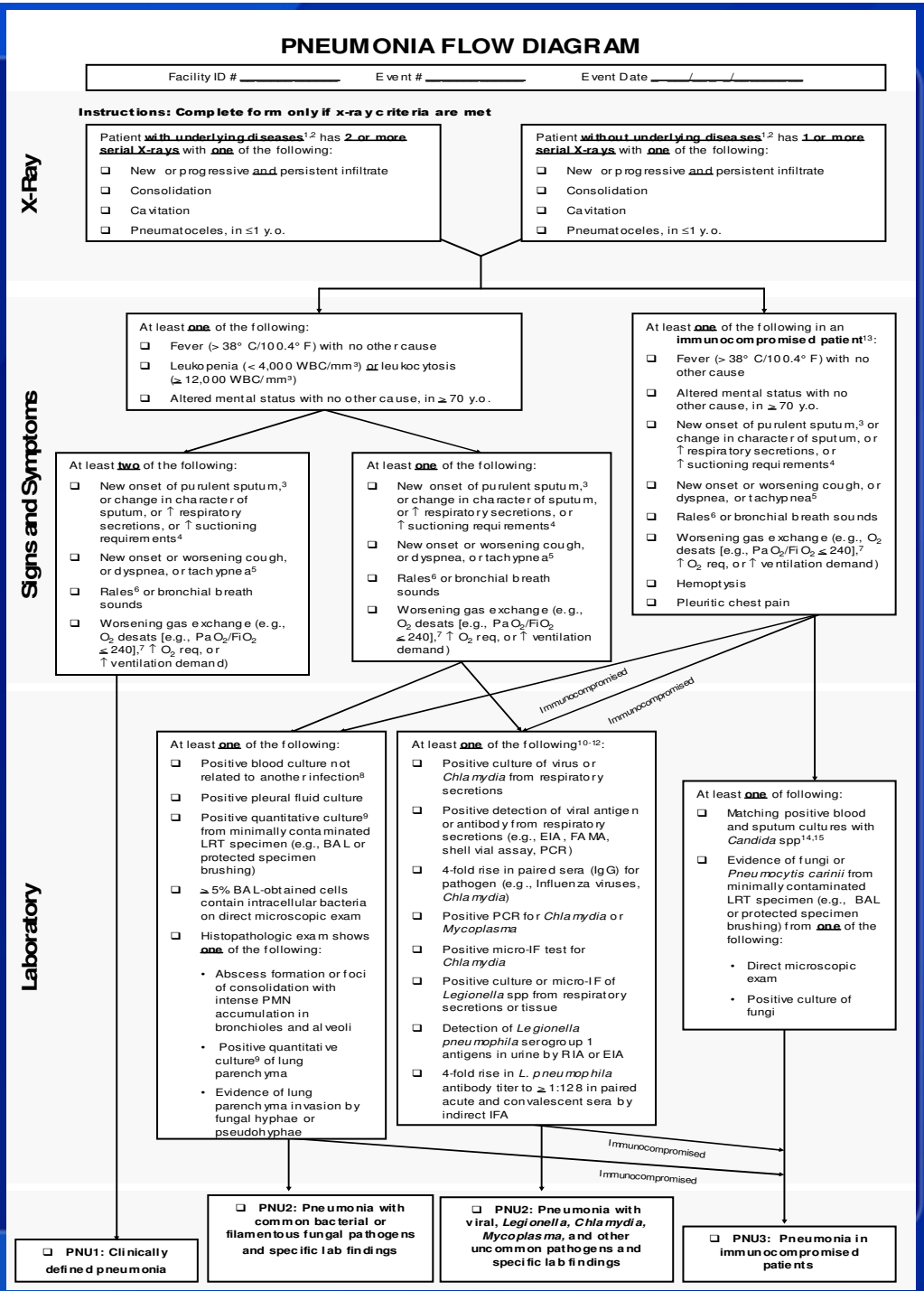
See NHSN Manual: Patient Safety Component Protocol , http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf

What about VAP?

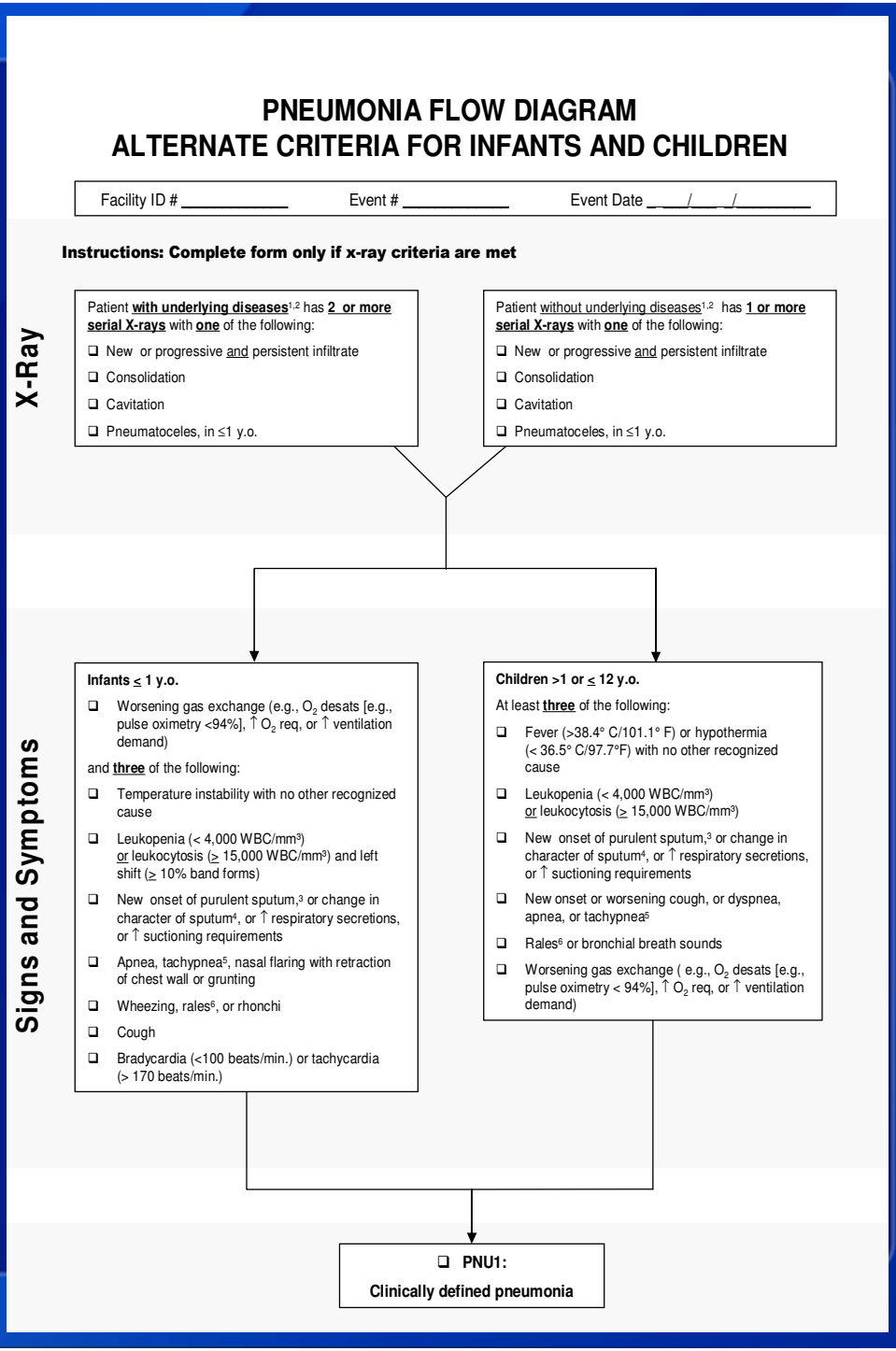
- **"VAP" is actually not a distinct definition in NHSN**
- **A VAP in NHSN is a PNEU event that meets the "ventilator-associated" criterion—**
  - Endotracheal tube (ETT)/ventilator must have been in place at some time during the 48 hours preceding the onset of PNEU
  - No required amount of time that the ETT/ventilator must have been in place for a PNEU to count as a VAP

See NHSN Manual: Patient Safety Component Protocol , http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf

NHSN PNEU flow diagram

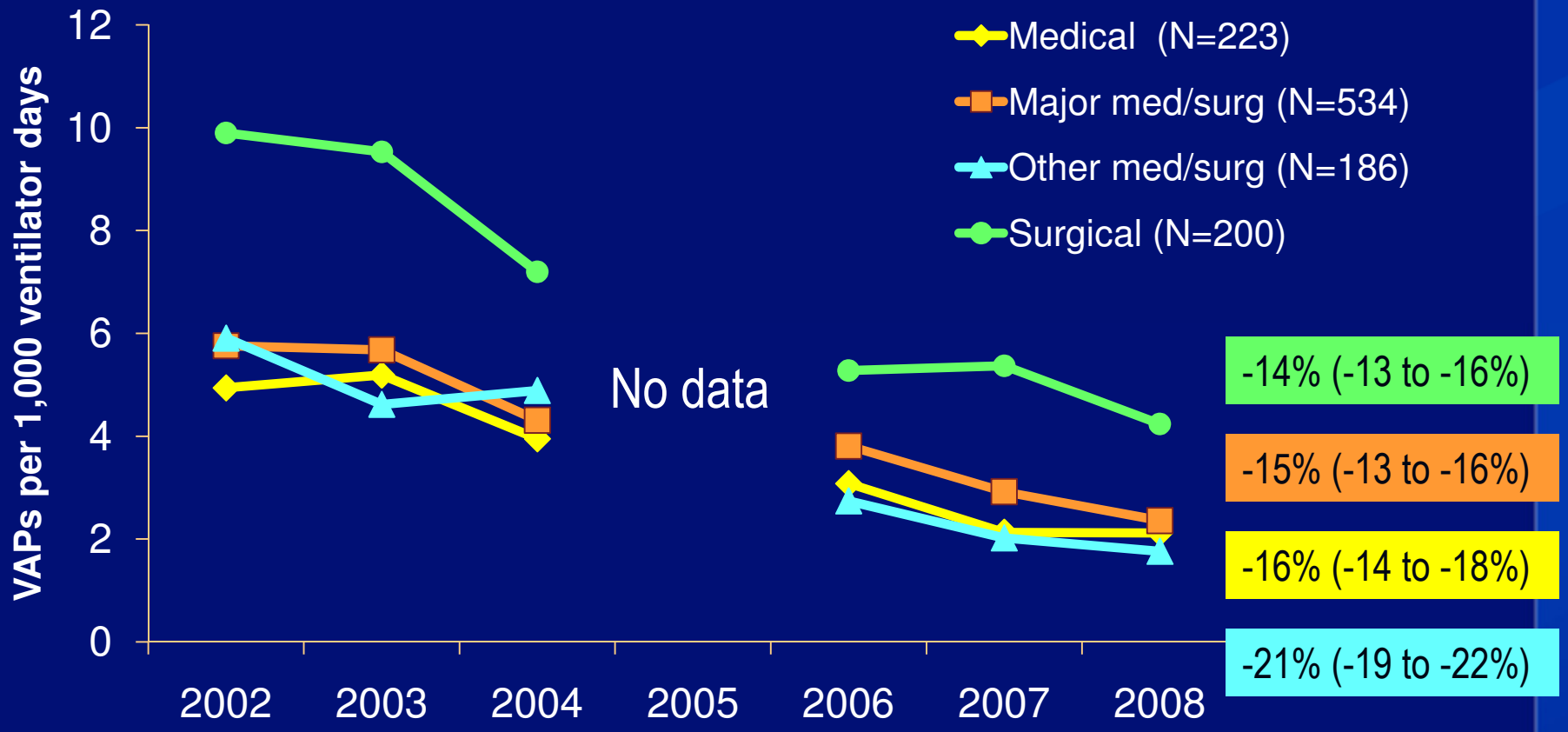


NHSN PNEU flow diagram: alternate PNU1 criteria for infants and children



What Do NHSN Data Tell Us about Trends in VAP Incidence Rates in Recent Years?

VAP Incidence Rates—All Reporting Facilities*



*Abstract available at: http://shea.confex.com/shea/2010/webprogram/Paper1745.html. Analysis updated since abstract submission. Numbers may vary.

- **So we are seeing dramatic declines in NHSN VAP incidence rates … can we conclude that the current PNEU (VAP) definitions are working well? Why the controversy? Why do we keep hearing about how difficult VAP is?**
  - Let's take a closer look …

Why are NHSN VAP Incidence Rates Declining?

- **Implementation of prevention strategies may be playing a role**
  - Publication of several prevention guidelines since 2002
  - Use of prevention bundle approach
- **But going forward, we must consider the following as well:**
  - Increased burden on infection preventionists
  - Definitions originally developed for internal quality improvement purposes (in a relatively small group of motivated facilities) now being used for benchmarking and public reporting—in potentially thousands of facilities
  - Potential for surveillance using these definitions to be gamed if healthcare facility reputations and compensation are linked to VAP rates

NHSN User Impressions of the PNEU Definitions

- **Overall**
  - **65%** say too complicated, too subjective, or too time-consuming
- **How should PNEU be used?**
  - **87%** – internal quality improvement
  - **62%** – benchmarking
  - **19% – mandatory public reporting**
- **What element of PNEU is essential to the definitions?**
  - **69-73%** – chest radiograph
  - And yet … users commented repeatedly about the difficulty of this element
- **Only 3% said they wouldn't change anything about PNEU**

Summary of PNEU Limitations

- **Multiple definition pathways increase complexity and data collection burden**
- **Signs and symptoms are subjective**
- **Chest radiographs are required – and outside scope of infection preventionist expertise**
  - Reliance on radiologists, critical care or other MD input varies among facilities
- **Diagnostic practice variations influence whether PNEU events are detected and reported**

Challenges in Diagnosing VAP: the Clinical Perspective

Many Complications of Critical Care Present with Clinical Signs that Can Mimic VAP

- **Radiographic opacities**[1]
  - Pneumonia
  - ARDS
  - Congestive heart failure
  - Atelectasis
  - Pulmonary infarction
- **Abnormal white blood cell count**
- **Impaired oxygenation**
- **Increased pulmonary secretions**
- **Fever**[1]
  - Pneumonia
  - Sinusitis
  - Bloodstream infection
  - UTI
  - Gall bladder disease
  - Empyema
  - Peritonitis
  - ARDS
  - Chemical aspiration
  - Pancreatitis
  - Drug fever

[1]Meduri et al, *Chest* 1994; 106:221-235

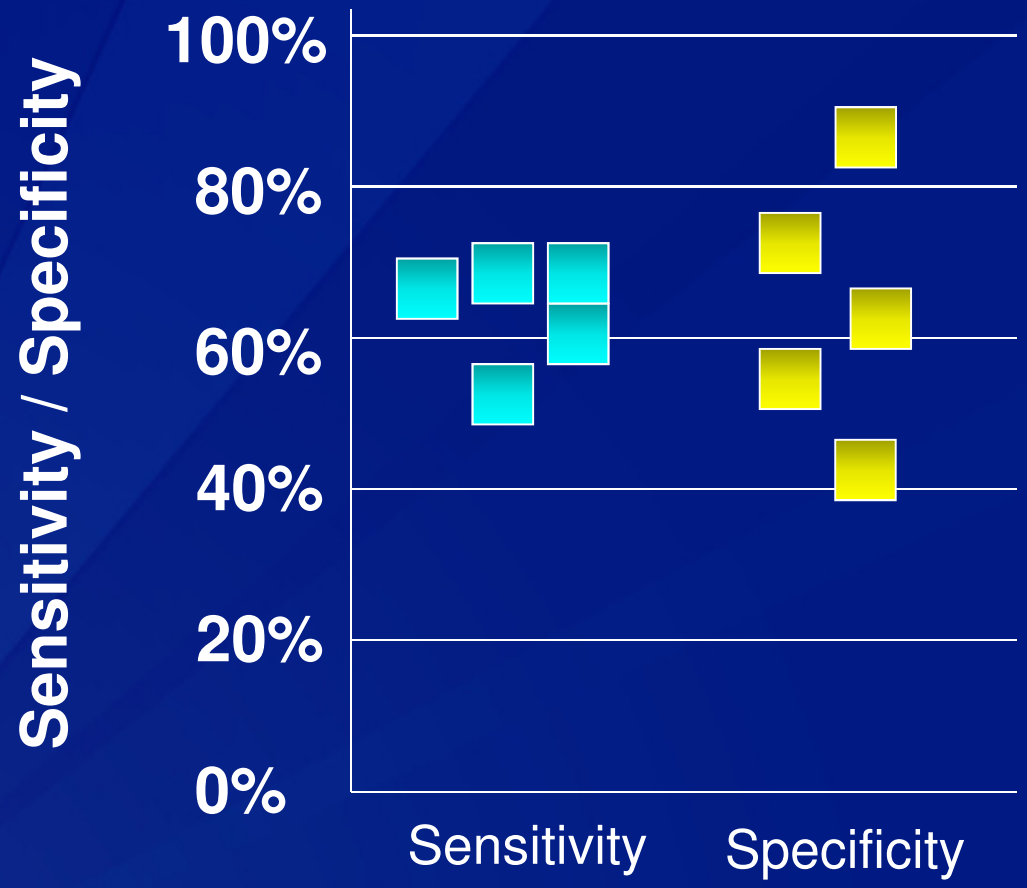
Slide content courtesy of Michael Klompas, MD, MPH, FRCPC

Physician Diagnosis Poor

- **Series of 84 ICU patients with abnormal chest x-rays and purulent sputum**
  - Evaluated by 7 physicians for VAP
  - "True diagnosis" established by histology or quantitative bronchoscopy cultures
  - 32% found to have VAP
  - Physicians disagreed on presence or absence of VAP in 35/84 (42%) of patients
    - The "best" doc missed 28% of true VAP's
    - The "worst" doc missed 50% of true VAP's
    - Both labeled ~20% of patients without VAP as having VAP

Fagon et al, *Chest* 1993; 103:547-53; slide courtesy of Michael Klompas, MD, MPH, FRCPC

Clinical Diagnosis of VAP vs. Autopsy
Sensitivity and Specificity



Torres, *Am J Resp Crit Care Med* 1994;149:324; Papazian, *Am J Resp Crit Care Med* 1995;152:1982; Fabregas, *Thorax* 1999;54:867; Wunderink, *Chest* 1992;101:458; Petersen, *Scand J Infect Dis* 1999;31:299

Slide courtesy of Michael Klompas, MD, MPH, FRCPC

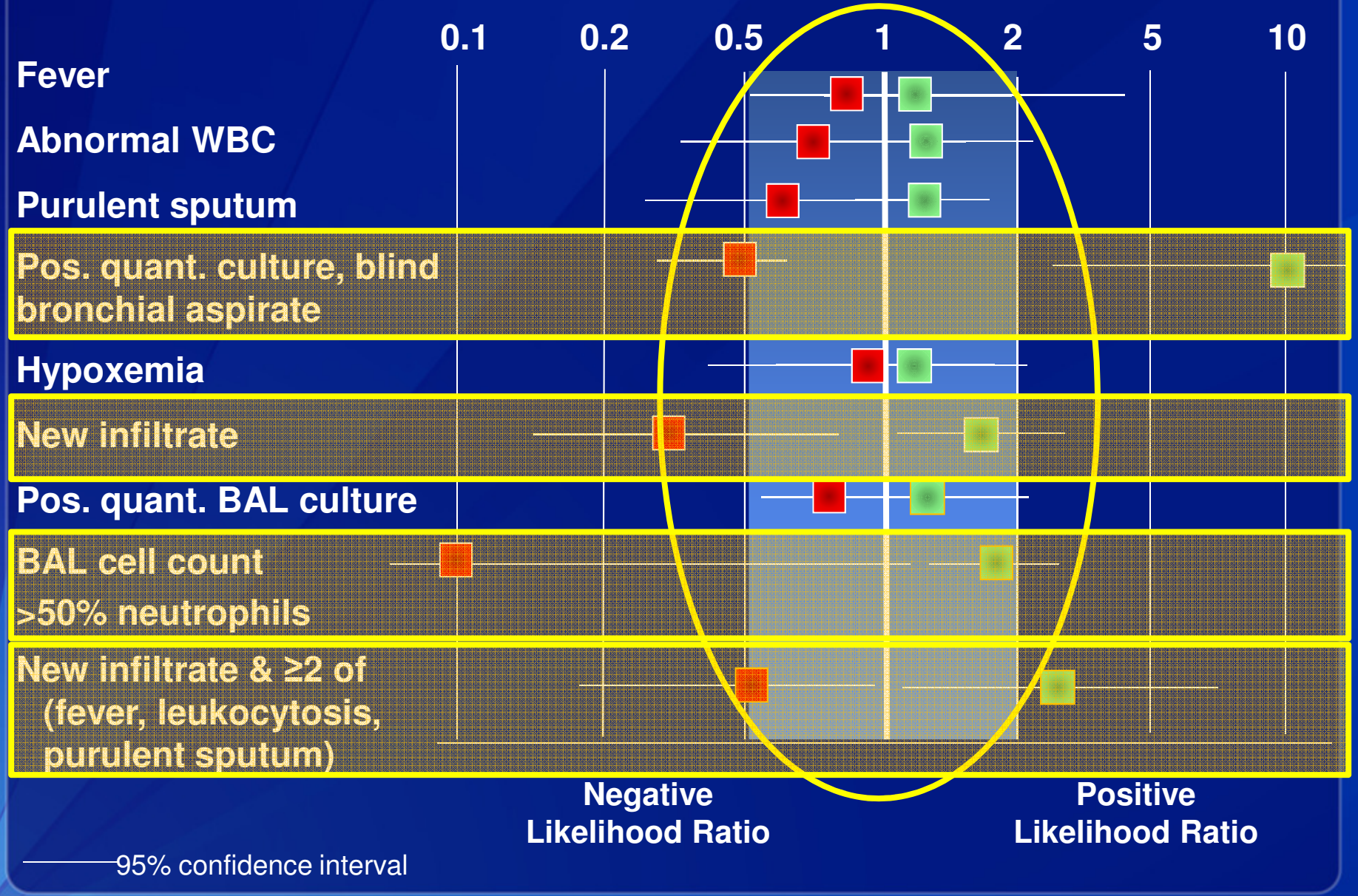
Evaluation of Clinical Signs to Diagnose VAP

- **Systematic search of Medline and Google Scholar to find English-language studies evaluating the accuracy of clinical, radiographic, and laboratory data to diagnose VAP relative to lung biopsy as gold standard**
  - 14 studies describing 655 patients

Klompas, *JAMA* 2007; 297:1583

Slide courtesy of Michael Klompas, MD, MPH, FRCPC

Accuracy of Clinical Signs for VAP



Slide content courtesy of Michael Klompas, MD, MPH, FRCPC

Klompas, *JAMA* 2007; 297:1583

Challenges in Defining VAP: the Surveillance Perspective

What are the Implications of Diagnostic Uncertainty for VAP Surveillance?

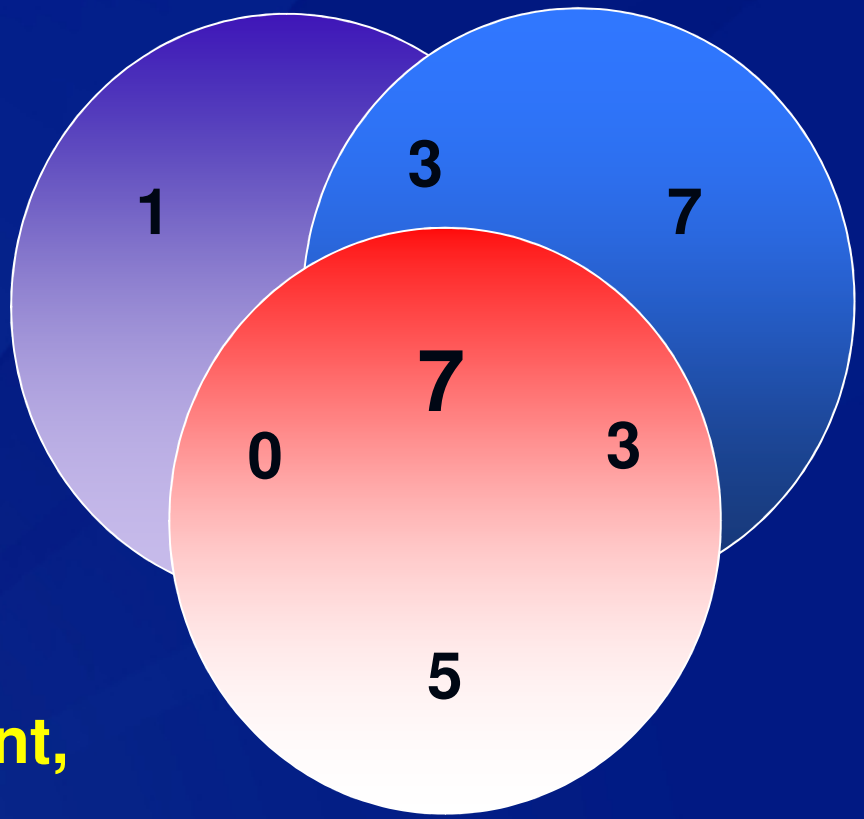
- **Different rates depending upon observer**
  - Interobserver agreement for NHSN VAP determinations is limited

Klompas, *AJIC* 2010:38:237; Morris, *Thorax* 2009;64:516; Klompas, Kulldorff, Platt. *Clin Infect Dis* 2008; 46:1443

Slide courtesy of Michael Klompas, MD, MPH, FRCPC

Interobserver Agreement in VAP Surveillance

50 ventilated patients with respiratory deterioration in 1 hospital; each patient reviewed by 3 IPs: 2 used conventional (C) approach, 1 used quantitative (Q) approach



62% agreement, Kappa = 0.40

Klompas, *AJIC* 2010:38:237

What are the Implications of Diagnostic Uncertainty for VAP Surveillance?

- **Different rates depending upon observer**
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- **Different rates depending upon diagnostic protocol**
  - Methods of sampling lower respiratory tract will impact on VAP rate

Klompas, *AJIC* 2010:38:237; Morris, *Thorax* 2009;64:516; Klompas, Kulldorff, Platt. *Clin Infect Dis* 2008; 46:1443

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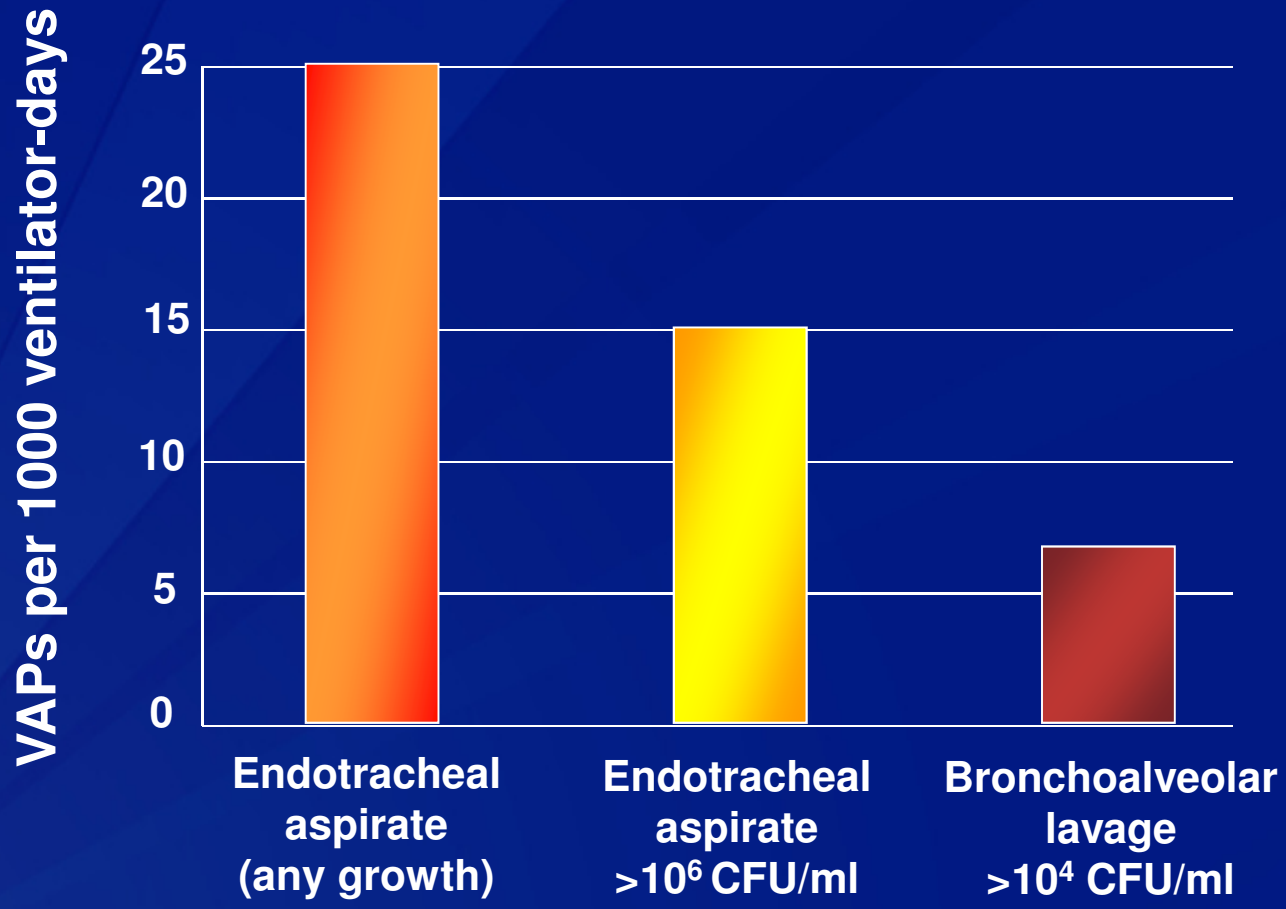
VAP Rates Vary with Diagnostic Technique

Modeled effect of exclusive use of endotracheal aspirates vs. BAL in an ICU over 12 month period



Slide courtesy of Michael Klompas, MD, MPH, FRCPC

Morris, *Thorax* 2009;64:516

What are the Implications of Clinical Diagnostic Uncertainty for VAP Surveillance?

- **Different rates depending upon observer**
  - Interobserver agreement for NHSN VAP determinations is poor
- **Different rates depending upon diagnostic protocol**
  - Methods of sampling lower respiratory tract will impact on VAP rate
- **Different rates depending upon the frequency of "mimicking" conditions in the ICU**
  - ICUs with higher prevalence of conditions such as ARDS, pulmonary edema, will end up having higher VAP rates because of the inaccuracy of diagnosis

Klompas, *AJIC* 2010:38:237; Morris, *Thorax* 2009;64:516; Klompas, Kulldorff, Platt. *Clin Infect Dis* 2008; 46:1443

Slide courtesy of Michael Klompas, MD, MPH, FRCPC

Impact of Diagnostic Uncertainty on VAP Surveillance Data

- **It's possible for a facility to lower its VAP rates without meaningfully improving patient care by doing the following:**
  - Narrowly interpret subjective clinical signs
  - Narrowly interpret chest radiographs
  - Seek consensus between multiple IP's
  - Allow clinicians to veto surveillance determinations
  - Increase use of quantitative BAL for diagnosis

Slide content courtesy of Michael Klompas, MD, MPH, FRCPC

What Is the Future of VAP Surveillance at CDC?

- **Recognize that current PNEU definitions won't work in the current environment**
  - Too burdensome
  - Too much variability in case finding
- **Recognize the inaccuracies in VAP diagnosis –much of what we are currently calling "VAP"—in NHSN or in other settings— is not VAP at all**
  - Validity is going to be a problem—no matter what
- **Focus on a surveillance definition that is objective, streamlined, reliable, and potentially automatable**
  - NOT a clinical definition—but ideally has clinical credibility

CDC Progress to Date

- Developed a simplified definition of ventilator-associated lower respiratory infection (VALORI) in collaboration with the CDC Prevention Epicenters investigators
- Evaluated VALORI in collaboration with the CDC Prevention Epicenters investigators
- Presented initial results for discussion and input at a Sept. 2nd experts meeting in Atlanta

Initial Draft VALORI Definition

- **Reflects work done/definitions developed by CDC Prevention Epicenters investigators[1,2]**
- **Eliminated chest imaging requirement**
- **Required minimum time on ventilator (4+ calendar days)**
- **Incorporated objective signs**
  - Pulmonary deterioration (measured by worsening oxygenation)
  - General signs of infection/inflammation (temp, WBC or purulent respiratory secretions)

[1]Klompas et al., Infect Control Hosp Epidemiol 2008;29:31-7; [2]Klompas et al., 5th Decennial International Conference on Healthcare-Associated Infections, Atlanta, GA, March18-22, 2010, abstract #741.

Preliminary VALORI Evaluations

- **CDC-led retrospective chart review assessment of VALORI data collection burden and agreement with current PNEU definitions**
- **Epicenters-led VALORI projects, adult patients**
  - Clinical analysis of VALORI+ and VAP+ patients
  - Comparison of outcomes for VALORI+ versus VALORI- and for VAP+ versus VAP- patients
  - Attributable length of stay and mortality of VALORI
- **Epicenters-led pediatric/neonatal VALORI focus group effort and chart review project**

Preliminary Results

- **VALORI surveillance appears to take less time than NHSN VAP surveillance**
- **VALORI and NHSN VAP definitions appear to detect different events**
  - In other words, not all VAP events meet the VALORI definition
  - VALORI detects more events than VAP
- **Clinical relevance of VALORI comparable to that of NHSN VAP**
  - Length of stay
  - Mortality
- **More work needed to modify VALORI for pediatric and neonatal populations**

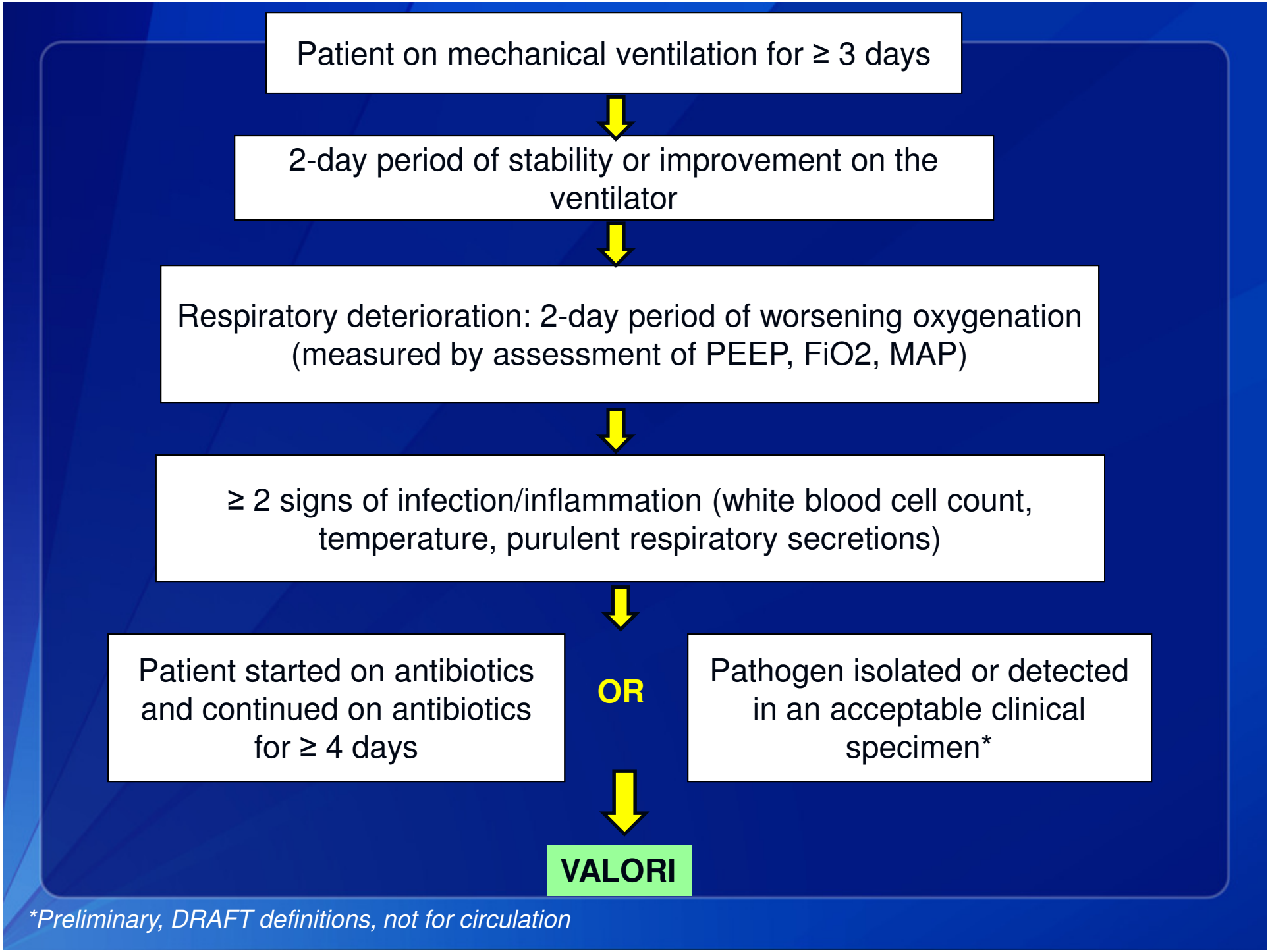
September 2nd Meeting Expert Feedback: Summary Points

- **VALORI departs from current practice—needs to be an infection measure, not just a severity of illness measure**
  - Issue of clinical credibility
- **Important to maintain chest imaging criterion and incorporate microbiological criteria —despite significant intra-facility and inter-facility variability**
- **Critical to demonstrate the preventability of any new measure**

Modified Draft VALORI And VAP Definitions*

Based on expert feedback

**Preliminary, DRAFT definitions, not for circulation*


Patient on mechanical ventilation for ≥ 3 days
2-day period of stability or improvement on the ventilator
Respiratory deterioration: 2-day period of worsening oxygenation (measured by assessment of PEEP, FiO2, MAP)
≥ 2 signs of infection/inflammation (white blood cell count, temperature, purulent respiratory secretions)
Patient started on antibiotics and continued on antibiotics for ≥ 4 days
OR
Pathogen isolated or detected in an acceptable clinical specimen*
VALORI
*Preliminary, DRAFT definitions, not for circulation

Modified Definition Allows for Reporting of "Probable VAP" Based on Chest Imaging Abnormalities

Patient meets VALORI definition

≥ 2 chest imaging studies that each show one or more of the following*: infiltrate, opacity, density, consolidation, cavitation, airspace disease, or pneumatoceles (neonates only)

Probable VAP

**Preliminary, DRAFT definitions, not for circulation*

Next Steps

- Receive additional feedback
- Make additional modifications
- Pilot modified definition
- Gain experience with definition in NHSN
- Submit to National Quality Forum for endorsement consideration

Acknowledgments

- **NNIS and NHSN facilities, users, patients**
- **Subject matter experts**
- **HHS Office of Healthcare Quality**
- **Epicenters Investigators and VALORI study collaborators**
  - Mike Klompas, Grace Lee, many others
- **CDC VALORI project:**
  - Participating facilities, Premier, Inc., Chicago Epicenter/ Stroger colleagues, expert reviewers
- **CDC/DHQP colleagues**

Thank you!

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.